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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,785	07/11/2005	Yoshinori Uji	M&M-080-USA-PCT	4129

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EXAMINER	
DAMRON, ANITA B	
ART UNIT	PAPER NUMBER
4112	
MAIL DATE	DELIVERY MODE
05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,785	UJI ET AL.	
	Examiner	Art Unit	
	ANITA DAMRON	4112	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/11/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This is the initial Office Action based on the 10541785 application filed July 11, 2005.

2. Claims 1-7 are pending and have been fully considered.

Information Disclosure Statement

3. The information disclosure statement filed July 11, 2005 fails to comply with 37CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7 are rejected under 35 U.S.C. 102(b) taught by KITAGAWA et al. (US Patent No. 6,241,886 B1).

6. KITAGAWA et al. teaches a plasma separation filter. Fibrinogen is separated from plasma in the specification Example 10 column 32 lines 34-35. With regard to

claim 1, a porous polymer filter comprising a fiber mass is taught in Example 1 of the Specification column 21 lines 65 through column 22 line 47. Furthermore table 2 cites filters with a total surface area range (A) of 2.0 to 3.9 m^2 with corresponding filling amounts ranging from 2 to 2.4 g. Ranges of surface areas in the table calculate as: 2.0 m^2/2.4 g = 1.95 m^2/g, and 3.9 m^2/2.0 g = 0.83 m^2/g where both values are well within the range of 0.5 m^2/g or larger. Calculating porosity % as pore volume/volume of fiber from table 2 yields a range of 55% to 77%, both within the range of 85% or lower.

7. With regard to claim 2, the reference examples of KITAGAWA et al. teach fibrinogen levels reduced 70% in examples 9 and 7, 80% in example 11, and 100% in example 10. Example 10 teaches that the fibrinogen content is about 220 mg/dl and the reference filter is 2g. Total blood proteins recovered in example 10 were 6.8 g/dl. The filter used is 2g in weight. 220 mg fibrinogen/2g filter is 100 mg per g of filter. 6.8g/dl proteins x 4% = 272 mg fibrinogen/2g of filter. In both calculations, the filter adsorbs the amount of 1mg or greater per g of filter.

8. With regard to claim 3, the referenced examples of KITAGAWA et al. 9, 10, and 11 used polyethylene terephthalate fibers, a polyester-based resin as the porous polymer.

9. With regard to claim 4, the method for removing fibrinogen is taught in examples 9, 10, 11, comparative example 7, and in, the specification column 14 line 26 through column 15 line 52 of KITAGAWA et al.

10. With regard to claim 5, a filter device for removing fibrinogen is taught in figures 6a and 6b and in the specification column 17 lines 20-54 of KITAGAWA et al. wherein

said device comprises a porous polymer in a container 15, a specific example being a syringe (tubular container).

11. With regard to claim 6, KITAGAWA et al. teaches at column 15 lines 55-61 of the specification that blood is supplied to a container, with pressuring means at the filtrate side. More specifically, a "separation filter, preferably blood supplying means for supplying blood to the filter, pressurizing means for pressurizing the supplied blood and/ or depressurizing means for reducing pressure at the filtrate side". When the member is pushed down, the blood is supplied to the filter and pressurized and thus plasma is separated. Figure 7 illustrates this. See also column 17 lines 41-54 of the specification.

12. With regard to claim 7, a plasmas separation method is taught in the specification column 14 line 26 though column 15 line 52, with fibrinogen being separated in Example 10 column 32 of the specification lines 34-35. A slidable pressurizing means 24 (piston) contacting liquid tightly with an internal peripheral all of the tubular container 15 is taught in the specification column 17 lines 22-24. A piston is cited in column 17 line 40. The pressurized blood is separated while passing through a micro fiber medium (fiber mass, microparticles or porous polymer) and plasmas is collected from a outlet (plasma suctioning opening in an opposite side to the side where the piston for the fiber mass is arranged is taught in the specification column 17 lines 26-28.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Japanese publications cite methods apparatus and/or filters for

separating blood serum, JP2000-309539, JP11-285607 and JP11-267463. US Patents teaching same 3,682,596 and 4,379,849.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANITA DAMRON whose telephone number is (571)270-5549. The examiner can normally be reached on Monday through Thursday 7:30 to 5:00 every other Friday 7:30 to 4:30.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara L. Gilliam can be reached on 571-272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anita Bucsay Damron

Art unit 4112

/Barbara L. Gilliam/
Supervisory Patent Examiner, Art Unit 4128